

Amendment re 10/7/04 Official Action
Application No. 10/632,281

REMARKS

Favorable reconsideration and allowance are respectfully requested. Claims 1-15 are pending. By this amendment, claim 3, 5 and 11 were canceled without prejudice to Applicants' right to pursue one or more divisional applications, and the remaining claims were amended to correct certain clerical errors in the claims and/or to address one or more of the rejections discussed below. Therefore, the amendments to the claims do not introduce new matter. Claims 1-2, 4, 6-10 and 12-15 remain pending and at issue.

Claim Objections & Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 5, 8, and 14-15 were objected to due to various formal matters. In addition, claims 1-4, 6-9, 10, and 11-15 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Each of these objections/rejections are discussed below:

- Various claims, e.g., claim 5, line 2, recited "comprising" in a Markush grouping which should include "consisting of" language. Appropriate correction of such irregularities have been made.
- Claim 8 referred to a "combination" rather than a "method". Accordingly, claim 8 has been amended to refer to a method according to Claim 1.
- Claims 14 and 15 were objected to because the claims should have referred to an "erbB tyrosine kinase inhibitor" rather than a "tyrosine kinase inhibitor". While the claims no longer refer to an "erbB tyrosine kinase inhibitor" for reasons that are discussed below, all references to tyrosine kinase inhibitors now include an appropriate modifier.
- Claim 10 was rejected as indefinite because it referred to "said cancer". Claim 9 has now been amended to refer to a method of treating cancer, so that there is proper antecedent basis in claim 10 for the reference to "said cancer".
- Claims 11-12 were rejected as indefinite because the claims referred to "CI-1033". The claims have been amended to refer to the proper compound name recited in claim 4.
- Claim 12 was rejected as indefinite because the claim referred to "taxotere" without sufficient antecedent basis. The claim has been amended accordingly.
- Claims 1 and 9 were rejected as indefinite because of the limitations "cell proliferative diseases" and "hyperproliferative cellular disorder". The Examiner stated that the specification does not clearly set forth the definition of these limitations and the metes and bounds of the patent protection desired are unclear. Without conceding the propriety of the rejection and purely in the interest of advancing prosecution on the merits, Applicants have amended the claims to refer to methods of treating cancer, rather than methods of treating cell proliferative diseases or methods of treating hyperproliferative cellular disorders.

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Rejections Under 35 U.S.C. §§ 102 & 103

Claims 1, 2, 5-8, 9-10, and 13-15 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by WO9931140 ("WO '140"). Further, claims 1-3, 5, and 9-10 were rejected under 35 U.S.C. § 102(a) as anticipated by WO 0241828 ("WO '828"). Finally, claims 1-4, 5, 11, and 12 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Rao et al. *Int. J. Radiation Oncology Biol. Phys.* Vol. 48 (5): 1519-28 (2000) ("Rao").

WO '140 was cited as a disclosure of a method for treating cancers characterized by an overexpression of ErbB2 comprising administering to the patient an effective amount of an anti-ErbB2 antibody in combination with a chemotherapeutic agent. Similarly, WO '828 was cited as a disclosure of a method of treating cancer by administering an erbB2 inhibitor alone or in combination with other anticancer agents. Finally, Rao was cited as a disclosure of a method of treating ErbB-over expressing human breast cancer cells with a combination of ionizing radiation and CI-1033.

Applicants traverse these rejections, addressed collectively below.

As to WO '140 and WO '828, the instant claims are notably different than the disclosures of the cited references because the claims are directed to the administration of a panerb inhibitor rather than an ErbB2-selective inhibitor. Therefore the claims are not anticipated by WO '140 or WO '828 because these references simply do not disclose the claimed invention.

With respect to Rao, the claims have been amended to delete the reference to the use of radiation in the claimed method. This amendment was made in an effort to advance prosecution and it should not be taken as an admission that the Examiner's rejection has merit. On the contrary, Applicants reserve the right to pursue the subject matter excised from the current claims in one or more pending divisional applications.

In view of the foregoing amendments and remarks, favorable reconsideration and withdrawal of the Sections 102 and 103 rejections are respectfully requested.

CONCLUSION

Favorable consideration of the foregoing amendments and remarks are respectfully requested. If, after consideration of these remarks the Examiner maintains that there are issues that remain an impediment to allowance, he is invited to telephone the undersigned to discuss such issues.

Respectfully submitted,



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